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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME CORP., PLAINTIFF, v. AUROBINDO PHARMA USA INC., AUROMEDICS PHARMA LLC, AND AUROBINDO PHARMA LTD., DEFENDANTS.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Merck Sharp & Dohme Corp. ("Merck" or "Plaintiff"), by and through its undersigned attorneys, for its Complaint against Defendants Aurobindo Pharma USA Inc., AuroMedics Pharma LLC, and Aurobindo Pharma Ltd. (together, "Aurobindo" or "Defendants") alleges, upon knowledge with respect to Defendants' acts and upon information and belief as to other matters, as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of U.S. Patent Nos. 9,023,790 (the "'790 Patent") and 9,358,297 (the "'297 Patent") arising under the patent laws of the United States, Title 35, United States Code, § 100 et seq., and in particular under 35 U.S.C. § 271(e). Aurobindo notified Merck pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "Notice Letter") that Aurobindo is the owner of Abbreviated New Drug Application ("ANDA") No. 214842, (the "Aurobindo ANDA"), which Aurobindo filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration ("FDA") for approval to engage in the commercial manufacture, use or sale of a generic version of Merck's NOXAFIL® (posaconazole) intravenous (infusion) solution, 300 mg/16.7 mL (18 mg/mL), which is sold in the United States. The Aurobindo posaconazole intravenous solution product described in the Aurobindo ANDA is referred to herein as the "Generic Posaconazole IV Solution Product."

THE PARTIES

2. Plaintiff Merck is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. Merck is a global, research-driven pharmaceutical company that discovers, develops, manufactures and markets a broad range of innovative products to improve health.

3. On information and belief, Defendant Aurobindo Pharma USA Inc. ("Aurobindo USA") is a company organized and existing under the laws of Delaware, having a principal place of business at 279 Princeton Hightstown Rd, East Windsor, New Jersey 08520-1401, USA. On information and belief Aurobindo USA develops, formulates, manufactures, markets and sells pharmaceutical drug products in the United States.

4. On information and belief, Aurobindo USA is a wholly-owned subsidiary of Aurobindo Pharma Ltd. ("APL").

5. On information and belief, Defendant AuroMedics Pharma LLC ("AuroMedics") is a company organized and existing under the laws of Delaware, having a principal place of business at 279 Princeton Hightstown Rd, East Windsor, New Jersey 08520-1401, USA. On information and belief AuroMedics develops, formulates, manufactures, markets and sells injectable pharmaceutical drug products in the United States.

6. On information and belief, AuroMedics is a wholly-owned subsidiary of APL.

7. On information and belief, APL is a corporation organized and existing under the laws of India with a principle place of business at Water Mark Building, Plot No. 11, Survey No. 9, Kondapur, Hi-Tech City, Hyderabad – 500084, Telangana, India. Further on information and belief, APL is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, distributing, and importing into the United States, generic versions of branded pharmaceutical drugs for the U.S. market, through various operating subsidiaries, including Aurobindo USA and AuroMedics.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a).

9. This Court has personal jurisdiction over Aurobindo USA by virtue of its presence in New Jersey, having conducted business in New Jersey, having its principal place of business in New Jersey, having availed itself of the rights and benefits of New Jersey law such that it should reasonably anticipate being haled into court in this judicial district, and having engaged in systematic and continuous contacts with the State of New Jersey through the marketing and sales of generic drug products within this judicial district, through the receipt of revenue from the sales and marketing of generic drug products within this judicial district, and through its pursuit of regulatory approval for its Generic Posaconazole IV Solution Product to market and sell its Generic Posaconazole IV Solution Product, if approved, in this judicial district and to residents of this judicial district, and having sent or caused to have sent the Notice Letter to Merck in New Jersey, prompting the filing of this lawsuit. *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 759–60 (Fed. Cir. 2016), *cert. denied sub nom. Mylan Pharm. v. Acorda Therapeutics*, 137 S. Ct. 625 (2017).

10. This Court has personal jurisdiction over AuroMedics by virtue of its presence in New Jersey, having conducted business in New Jersey, having its principal place of business in New Jersey, having availed itself of the rights and benefits of New Jersey law such that it should reasonably anticipate being haled into court in this judicial district, and having engaged in systematic and continuous contacts with the State of New Jersey through the marketing and sales of generic drug products within this judicial district, through the receipt of revenue from the sales and marketing of generic drug products within this judicial district, and through its pursuit of regulatory approval for its Generic Posaconazole IV Solution Product to market and sell its Generic Posaconazole IV Solution Product, if approved, in this judicial district and to residents

of this judicial district, and having sent or caused to have sent the Notice Letter to Merck in New Jersey, prompting the filing of this lawsuit. *Id.*

11. This Court has personal jurisdiction over APL by virtue of its presence in New Jersey, having conducted business in New Jersey, having availed itself of the rights and benefits of New Jersey law such that it should reasonably anticipate being haled into court in this judicial district, and having engaged in systematic and continuous contacts with the State of New Jersey through the marketing and sales of generic drug products within this judicial district, through the receipt of revenue from the sales and marketing of generic drug products within this judicial district, and through its pursuit of regulatory approval for its Generic Posaconazole IV Solution Product to market and sell its Generic Posaconazole IV Solution Product, if approved, in this judicial district and to residents of this judicial district, and having sent or caused to have sent the Notice Letter to Merck in New Jersey, prompting the filing of this lawsuit. *Id.*

12. Although this Court has personal jurisdiction over APL for at least the reasons set forth in Paragraph 11, in the absence of such personal jurisdiction in any single state, a foreign entity such as APL is subject to jurisdiction throughout the United States. *See* Fed. R. Civ. P. 4(k)(2); *Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1293–94 (Fed. Cir. 2012).

13. Venue is proper in this judicial district as to Aurobindo USA under 28 U.S.C. § 1400(b) because, *inter alia*, it has committed an act of infringement—including having sent or caused to have sent the Notice Letter to Merck this judicial district—and has a regular and established place of business in this judicial district.

14. Venue is proper in this judicial district as to AuroMedics under 28 U.S.C. § 1400(b) because, *inter alia*, it has committed an act of infringement—including having sent or

caused to have sent the Notice Letter to Merck this judicial district—and has a regular and established place of business in this judicial district.

15. Venue is proper as to APL in this judicial district under 28 U.S.C. § 1391(c)(3) because APL is a foreign entity who may be sued in any judicial district. *See In re HTC Corp.*, 889 F.3d 1349, 1357 (Fed. Cir. 2018).

NOXAFIL®

16. Merck is the holder of New Drug Application ("NDA") N205596 for the manufacture and sale of posaconazole intravenous solution, which Merck markets and sells under the registered trademark NOXAFIL® ("NOXAFIL® for Injection"). NOXAFIL® for Injection is approved for the prophylaxis of invasive fungal infections in high risk patients.

17. NOXAFIL® for Injection is an embodiment of one or more claims of the '790 Patent and the '297 Patent (collectively, the "Patents-in-Suit"). The Patents-in-Suit are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for NOXAFIL®.

PATENTS-IN-SUIT

18. The '790 Patent, entitled "Posaconazole Intravenous Solution Formulations Stabilized by Substituted β-Cyclodextrin," was duly and legally issued by the USPTO on May 5, 2015. The Orange Book lists the expiration date of the '790 Patent as July 4, 2031. Merck is the owner of all title, right and interest in and to the '790 Patent by assignment. A copy of the '790 Patent is attached as **Exhibit A**.

19. The '297 Patent, entitled "Posaconazole Intravenous Solution Formulations Stabilized by Substituted β-Cyclodextrin" was duly and legally issued by the USPTO on June 7, 2016. The Orange Book lists the expiration date of the '297 Patent as June 24, 2031. Merck is

the owner of all title, right and interest in and to the ’297 Patent by assignment. A copy of the ’297 Patent is attached as **Exhibit B**.

AUROBINDO’S ANDA

20. Aurobindo filed or caused to be filed the Aurobindo ANDA with the FDA, seeking FDA approval to market and sell within the United States the Generic Posaconazole IV Solution Product before the expiration of the Patents-in-Suit.

21. On information and belief, the Aurobindo ANDA identified Merck’s NOXAFIL® for Injection product and included a written certification, as required by 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the claims of the Patents-in-Suit are invalid or otherwise will not be infringed by the Generic Posaconazole IV Solution Product.

22. On or about July 2, 2020, Merck received the Notice Letter from Aurobindo, dated July 1, 2020, stating that pursuant to § 505(j)(2)(B)(ii) of the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 355(j)(2)(B)(ii), Aurobindo had submitted the Aurobindo ANDA to the FDA.

23. In its letter to Merck, Aurobindo stated its allegation that the claims of the Patents-in-Suit are invalid.

24. Aurobindo does not contest that Claims 1–19 of the ’790 Patent and Claims 1–34 of the ’297 Patent would be infringed by the manufacture, use, or sale of the Generic Posaconazole IV Solution Product, unless those claims are found to be invalid.

25. By filing or causing to be filed the Aurobindo ANDA, Aurobindo necessarily represented to the FDA that the Generic Posaconazole IV Solution Product has the same active ingredient as NOXAFIL® for Injection, has the same method of administration, dosage form, and strength as NOXAFIL® for Injection and is bioequivalent to NOXAFIL® for Injection.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 9,023,790

26. Merck incorporates by reference Paragraphs 1–25 of this Complaint as if fully set forth herein.

27. By filing or causing to be filed the Aurobindo ANDA with the FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use or sale of the Generic Posaconazole IV Solution Product before the expiration of the '790 Patent, Aurobindo committed an act of infringement under 35 U.S.C. § 271(e)(2).

28. If Aurobindo commercially makes, uses, offers to sell or sells the Generic Posaconazole IV Solution Product within the United States, or imports the Generic Posaconazole IV Solution Product into the United States, or induces or contributes to any such conduct during the term of the '790 Patent, Aurobindo would further infringe the '790 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

29. Aurobindo's commercial manufacture, use, offer to sell, or sale of the Generic Posaconazole IV Solution Product within the United States, or importation of the Generic Posaconazole IV Solution Product into the United States, during the term of the '790 Patent, would infringe the '790 Patent.

30. Upon approval of the Aurobindo ANDA, and the commercial marketing of the Generic Posaconazole IV Solution Product, Aurobindo would actively induce and/or contribute to infringement of the '790 Patent. At least in light of the prescribing instructions Aurobindo proposes to provide in connection with the Generic Posaconazole IV Solution Product, Aurobindo will induce health care professionals, resellers, pharmacies, and end users of the Generic Posaconazole IV Solution Product to directly infringe one or more claims of the '790

Patent. Aurobindo will encourage acts of direct infringement with knowledge of the '790 Patent and knowledge that it is encouraging infringement.

31. Aurobindo had actual and constructive knowledge of the '790 Patent prior to filing the Aurobindo ANDA, and was aware that the filing of the Aurobindo ANDA with the request for FDA approval before the expiration of the '790 Patent would constitute an act of infringement of the '790 Patent.

32. Merck will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Merck has no adequate remedy at law.

COUNT II FOR INFRINGEMENT OF U.S. PATENT NO. 9,358,297

33. Merck incorporates by reference Paragraphs 1–25 of this Complaint as if fully set forth herein.

34. By filing or causing to be filed the Aurobindo ANDA with the FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use or sale of the Generic Posaconazole IV Solution Product before the expiration of the '297 Patent, Aurobindo committed an act of infringement under 35 U.S.C. § 271(e)(2).

35. If Aurobindo commercially makes, uses, offers to sell or sells the Generic Posaconazole IV Solution Product within the United States, or imports the Generic Posaconazole IV Solution Product into the United States, or induces or contributes to any such conduct during the term of the '297 Patent, Aurobindo would further infringe the '297 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

36. Aurobindo's commercial manufacture, use, offer to sell, or sale of the Generic Posaconazole IV Solution Product within the United States, or importation of the Generic

Posaconazole IV Solution Product into the United States, during the term of the '297 Patent, would infringe the '297 Patent.

37. Upon approval of the Aurobindo ANDA, and the commercial marketing of the Generic Posaconazole IV Solution Product, Aurobindo would actively induce and/or contribute to infringement of the '297 Patent. At least in light of the prescribing instructions Aurobindo proposes to provide in connection with the Generic Posaconazole IV Solution Product, Aurobindo will induce health care professionals, resellers, pharmacies, and end users of the Generic Posaconazole IV Solution Product to directly infringe one or more claims of the '297 Patent. Aurobindo will encourage acts of direct infringement with knowledge of the '297 Patent and knowledge that it is encouraging infringement.

38. Aurobindo had actual and constructive knowledge of the '297 Patent prior to filing the Aurobindo ANDA, and was aware that the filing of the Aurobindo ANDA with the request for FDA approval before the expiration of the '297 Patent would constitute an act of infringement of the '297 Patent.

39. Merck will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Merck has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment in its favor and against Defendants and respectfully requests the following relief:

A. A judgment that Defendants have infringed one or more claims of the '790 Patent under 35 U.S.C. § 271(e)(2) by submitting the Aurobindo ANDA;

B. A judgment that Defendants have infringed one or more claims of the ’297 Patent under 35 U.S.C. § 271(e)(2) by submitting the Aurobindo ANDA;

C. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining Defendants, their officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, from making, using, selling, offering to sell, or importing any product that infringes the ’790 Patent, including the product described in the Aurobindo ANDA, prior to the expiration of the ’790 Patent, including any extensions;

D. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining Defendants, their officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, from making, using, selling, offering to sell, or importing any product that infringes the ’297 Patent, including the product described in the Aurobindo ANDA, prior to the expiration of the ’297 Patent, including any extensions;

E. A judgment declaring that making, using, selling, offering to sell, or importing the product described in the Aurobindo ANDA, or inducing or contributing to such conduct, would constitute infringement of the ’790 Patent by Defendants pursuant to 35 U.S.C. § 271;

F. A judgment declaring that making, using, selling, offering to sell, or importing the product described in the Aurobindo ANDA, or inducing or contributing to such conduct, would constitute infringement of the ’297 Patent by Defendants pursuant to 35 U.S.C. § 271;

G. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Aurobindo ANDA be a date that is not earlier than the expiration of the ’790 Patent or any later expiration of exclusivity to which Plaintiff is or

becomes entitled;

H. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Aurobindo ANDA be a date that is not earlier than the expiration of the '297 Patent or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

I. If Defendants, their officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active concert or participation with any of them commercially manufactures, uses, offers to sell, sells or imports the product described in the Aurobindo ANDA prior to the expiration of the '790 Patent or any later expiration of exclusivity to which Plaintiff is or becomes entitled, a judgment awarding Plaintiff monetary relief, together with interest;

J. If Defendants, their officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, or those persons in active concert or participation with any of them commercially manufactures, uses, offers to sell, sells or imports the product described in the Aurobindo ANDA prior to the expiration of the '297 Patent or any later expiration of exclusivity to which Plaintiff is or becomes entitled, a judgment awarding Plaintiff monetary relief, together with interest;

K. A declaration that this case is exceptional within the meaning of 35 U.S.C. § 285 and awarding reasonable attorneys' fees, costs and disbursement incurred as a result of this action; and

L. Such other and further relief as the Court deems just and proper.

* * *

Dated: August 13, 2020

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

By: /s/ *John E. Flaherty*
John E. Flaherty

CERTIFICATION PURSUANT TO L. CIV. R. 201.1(d)

Pursuant to Local Civil Rule 201.1, I hereby certify the above-captioned matter is not subject to compulsory arbitration in that, *inter alia*, the Plaintiff seeks non-monetary injunctive relief and the amount in controversy exceeds the $150,000 threshold of interest and costs and any claim for punitive damages.

By: /s/ *John E. Flaherty*
John E. Flaherty